

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ROBERT J. PEACH ET AL.

PATENT NO: 7,094,874

ISSUED: AUGUST 22, 2006

FOR: SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

FILING VIA EFS-WEB

Mail Stop: PETITIONS

Director, U.S. Patent & Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Sir:

This is a request for further reconsideration of patent term adjustment on U.S. patent No. 7,094,874. The Office of Petitions recently determined that the patent term adjustment should be 261 days. However, in view of recent legal developments and as explained below, the patent term adjustment should be 696 days.

*The Patent Office Applied an Improper Method of Calculating PTA*

The U.S. District Court for the District of Columbia recently held that the Patent Office has been applying an improper method of calculating patent term adjustment.

*Wyeth v. Dudas*, 2008 WL 4445642 (D.D.C. September 30, 2008). The Patent Office applied that improper method in the present case, resulting in a 435 day error.

The statute governing patent term adjustment, 35 U.S.C. § 154(b), defines certain periods of Patent Office delay that give rise to extensions of patent term. These include an "A period" concerning Patent Office failure to comply with certain deadlines (defined by 35 U.S.C. § 1.54(b)(1)(A)) and a "B period" concerning Patent Office failure to issue a patent within 3 years after the actual filing date of a patent application (defined by 35 U.S.C. § 1.54(b)(1)(B)).

In *Wyeth*, the Patent Office argued that any administrative delay under the A period overlaps any 3-year maximum pendency delay under the B period, such that delays should be credited to the A period or B period, but not to both periods. The court rejected that argument. It held that delays may be credited to both the A period and B period, except to the extent those periods overlap by occurring on the same calendar days.

In view of *Wyeth*, Petitioners request reconsideration of the patent term adjustment for the subject patent.

*Calculation of the B Period*

The patent term adjustment history from PAIR (attached as Appendix A) shows an adjustment of 84 days for the B period. However, the B period should be 519 days.

Relevant dates for calculating the B period are listed below.

Application Filing Date: May 23, 2001

3-year Anniversary of Filing: May 23, 2004

Request for Continued Examination: October 24, 2005

Patent Issue Date: August 22, 2006

The patent issue date was 821 days after the 3-year anniversary of the filing date. However, time consumed by examination after a request for continued examination does not count toward the B period. In this case, 302 days elapsed from the filing of a request for continued examination until the patent issued. So the B period is calculated as follows: 821 days - 302 days = 519 days. That is a difference of 435 days when compared with the Patent Office's improper 84 day calculation.

*The Director Should Add 435 More Days to the Patent Term Adjustment*

Considering the corrected B period, the Director should add 435 more days to the patent term adjustment. The B period delays did not occur on the same calendar days as the A period delays. In particular, the 519 day B period delay (beginning May 23, 2004 on the three-year anniversary of the filing date and ending October 24, 2005 on the filing of a request for continued examination) did not overlap with either the 435 day delay (ending

October 1, 2003 on the mailing of a restriction requirement) or the 24 day delay (ending August 22, 2006 on issuance of the patent)<sup>1</sup> that constitute the A period.

Accordingly, Petitioners request 435 more days of patent term adjustment, bringing the total patent term adjustment to 696 days ( $261 + 435 = 696$ ). The patent is not subject to any terminal disclaimer that would impact such a correction.

*Timeliness of this Request*

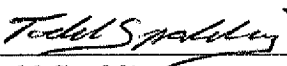
This request is being filed within two months of a decision by the Office of Petitions (attached as Appendix B) concerning patent term adjustment on the subject patent. Petitioners acknowledge that the request does not respond to any point made in that decision and that it is being filed more than two months after issuance of the patent. However, Petitioners timely raised the patent term adjustment issue in a previous paper and have promptly filed this further request after (a) the recent decision by the Office of Petitions and (b) the *Wyeth* decision. The specific arguments made in this request could not have been made earlier. Accordingly, the request is timely.

*Payment of Any Required Fees*

If any fees are required for consideration of this request, please charge them to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
Tel. No. (609) 252-3034

  
\_\_\_\_\_  
Todd Spalding  
Attorney for Applicants  
Reg. No. 55,638

Date: November 21, 2008

---

<sup>1</sup> Petitioners note that the 24 day delay occurred more than three years after the application was filed but after the filing of a request for continued examination. Because time after a request for reconsideration does not count toward the B period (even though it is beyond the three year date), there is no overlap of calendar days.

**Appendix A -  
Patent Term Adjustment History for  
U.S. Patent No. 7,094,874 (U.S. Patent Application No. 09/865,321)**

09/865,321

SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

11-19-

2008::15:16:02

**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 09/865,321

Filing or 371(c) Date:	05-23-2001	USPTO Delay (PTO) Delay (days):	543
Issue Date of Patent:	08-22-2006	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	290
Post-Issue Petitions (days):	+0	Total PTA (days):	261
USPTO Adjustment(days):	8	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
09-30-2008	Record a Petition Decision of Granted for Patent Term Adjustment after Issue		
09-26-2007	Adjustment of PTA Calculation by PTO	81	
02-21-2007	Mail-Record a Petition Decision of Granted for Patent Term Adjustment after Issue	↑	
02-20-2007	Adjustment of PTA Calculation by PTO		81
02-20-2007	Adjustment of PTA Calculation by PTO	8	
08-02-2006	PTA 36 Months	84	
08-22-2006	Patent Issue Date Used in PTA Calculation	24	
07-12-2006	Dispatch to FDC	↑	
06-09-2006	Workflow - Drawings Finished		75
06-01-2006	Miscellaneous Communication to Applicant - No Action Count		↑
05-31-2006	Sequence Forwarded to Pubs on Tape		↑
05-11-2006	Workflow - Drawings Finished		29
04-27-2006	Mail Examiner Interview Summary (PTOL - 413)		↑
04-27-2006	Mail Miscellaneous Communication to Applicant		↑
04-26-2006	Miscellaneous Communication to Applicant - No Action Count		
04-19-2006	Examiner Interview Summary Record (PTOL - 413)		
04-20-2006	TC Return to Pubs		
04-20-2006	Miscellaneous Incoming Letter		8
04-08-2006	Pubs Case Remand to TC		
04-05-2006	Application Is Considered Ready for Issue		
04-04-2006	Correspondence Address Change		
03-29-2006	Issue Fee Payment Verified		
03-29-2006	Issue Fee Payment Received		
03-29-2006	Sequence Forwarded to Pubs on Tape		
03-21-2006	Mail Notice of Allowance		
03-13-2006	Notice of Allowance Data Verification Completed		
01-13-2006	Information Disclosure Statement considered		
01-23-2006	Information Disclosure Statement considered		

01-13-2006	Information Disclosure Statement considered		
12-05-2005	Information Disclosure Statement considered		
10-24-2005	Information Disclosure Statement considered		
01-13-2006	Information Disclosure Statement (IDS) Filed		
01-23-2006	Information Disclosure Statement (IDS) Filed		10
02-01-2006	Date Forwarded to Examiner		↑
01-13-2006	Response after Non-Final Action		↑
01-13-2006	Request for Extension of Time - Granted		
01-13-2006	Information Disclosure Statement (IDS) Filed		
01-19-2006	IFW TSS Processing by Tech Center Complete		
12-05-2005	Reference capture on IDS		
12-05-2005	Information Disclosure Statement (IDS) Filed		
11-14-2005	Mail Notice of Informal or Non-Responsive RCE Amendment		
11-10-2005	Notice of Informal or Non-Responsive RCE Amendment.		
10-24-2005	Information Disclosure Statement (IDS) Filed		
11-10-2005	Date Forwarded to Examiner		
11-10-2005	Date Forwarded to Examiner		
10-24-2005	Request for Continued Examination (RCE)		
11-10-2005	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		
10-24-2005	Request for Extension of Time - Granted		
10-24-2005	Workflow - Request for RCE - Begin		
03-24-2005	Notice of Appeal Filed		87
03-24-2005	Request for Extension of Time - Granted		↑
01-10-2005	Mail Advisory Action (PTOL - 303)		↑
01-06-2005	Advisory Action (PTOL-303)		↑
12-10-2004	Date Forwarded to Examiner		↑
11-29-2004	Amendment after Final Rejection		↑
12-08-2004	Correspondence Address Change		↑
11-29-2004	Workflow incoming amendment IFW		↑
11-29-2004	Workflow incoming amendment IFW		↑
09-27-2004	Mail Final Rejection (PTOL - 326)		↑
09-24-2004	Final Rejection		
07-24-2004	Date Forwarded to Examiner		
07-19-2004	Response after Non-Final Action		42
07-19-2004	Workflow incoming amendment IFW		↑
06-18-2004	Mail Notice of Informal or Non-Responsive Amendment		↑
06-17-2004	Date Forwarded to Examiner		↑
06-07-2004	Informal or Non-Responsive Amendment after Examiner Action		↑
06-07-2004	Response after Non-Final Action		39

[illegible]

07-03-2002	Application Dispatched from OIPE	↑
07-02-2002	Application Is Now Complete	↑
09-20-2001	CRF Is Good Technically / Entered into Database	↑
06-11-2001	Notice Mailed--Application Incomplete--Filing Date Assigned	↑
06-11-2001	Correspondence Address Change	↑
06-01-2001	IFW Scan & PACR Auto Security Review	↑
05-23-2001	Initial Exam Team nn	↑

---

**Close Window**



**Appendix B -**

**Decision on Request for Reconsideration of Decision on Request for Reconsideration of  
Patent Term Adjustment and Notice of Intent to issue Certificate of Correction**



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450  
www.uspto.gov

Paper No.

LOUIS J. WILLE  
BRISTOL-MYERS SQUIBB COMPANY  
PATENT DEPARTMENT  
P O BOX 4000  
PRINCETON NJ 08543-4000

**COPY MAILED**

**OCT 01 2008**

**OFFICE OF PETITIONS**

In re Patent No. 7,094,874	:	DECISION ON REQUEST
Peach et al.	:	FOR RECONSIDERATION OF
Issue Date: August 22, 2006	:	DECISION ON
Application No. 09/865,321	:	REQUEST FOR
Filed: May 23, 2001	:	RECONSIDERATION OF
Atty Docket No. D0028PNP;	:	PATENT TERM ADJUSTMENT
30436.57USU1	:	and
	:	NOTICE OF INTENT TO ISSUE
	:	CERTIFICATE OF CORRECTION

This is a decision on the "RESPONSE TO DECISION ON SECOND REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT" filed February 29, 2008. Patentees request that the revised Patent Term Adjustment shown on the above captioned patent (and on the Certificate of Correction issued March 27, 2007) be corrected to two hundred sixty-one (261) days.

The second request for reconsideration of the decision of February 21, 2007 is GRANTED.

The patent term adjustment indicated in the patent is to be corrected by issuance of another certificate of correction showing a revised Patent Term Adjustment of two hundred sixty-one (261) days.

On August 22, 2006, the above-identified application matured into U.S. Patent No. 7,094,874 with a revised patent term adjustment of 253 days. By decision mailed February 21, 2007, the request for reconsideration of patent term adjustment filed October 20, 2006 was granted-in-part. By certificate of correction issued March 27, 2007, the patent term adjustment indicated in the patent was corrected to ONE HUNDRED EIGHTY

(180) days. This correction was based in part on entry of a period of reduction of 81 days pursuant to 37 CFR 1.704(c)(7).

The 81-day reduction is at issue. The decision mailed February 21, 2007 entered the reduction on the basis that the response filed October 24, 2005 included an omission as reflected by the mailing of a Notice of Non-compliant Amendment on November 14, 2005. As the further response correcting the omission was filed on January 13, 2006, a period of reduction of 81 days was entered.

Patentees' arguments as set forth on instant request for reconsideration, in light of the Office's action at the time of filing of the paper on January 13, 2006, has been reconsidered and found persuasive. It is concluded that entry of a period of reduction of 81 days on decision on request for reconsideration of patent term adjustment was not warranted.

Accordingly, the decision on application for patent term adjustment has been reconsidered and the reinstatement of 81 days of patent term is granted.

The \$200.00 fee set forth in 37 CFR 1.18(e) was submitted on request for reconsideration of patent term adjustment filed October 20, 2006. No additional fees are required.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue another certificate of correction indicating that the term of the above-identified patent is extended or adjusted by two hundred sixty-one (261) days.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3219.



Nancy Johnson  
Senior Petitions Attorney  
Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT : 7,094,874 B2

DATED : August 22, 2006

DRAFT

INVENTOR(S) : Peach et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[\*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 253 days

Delete the phrase "by 253 days" and insert -- by 261 days--